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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/051,843	06/29/98	WILLSON	T 11373

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EXAMINER	
BASI,N	
ART UNIT	**PAPER NUMBER**
1646	14

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/051,843	Wilson et al
Examiner	**Group Art Unit**
Nirmal. S. Basi	1646

☒ Responsive to communication(s) filed on *Jan 10, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-35* is/are pending in the application.

Of the above, claim(s) *11-24, 26, 27, and 31-35* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-10, 25, and 28-30* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-35* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: *PN-6135, PN-7276 and PO-2208* .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6, 7 and 10*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

1. Response to Restriction 1/10/00 has been entered.

Election/Restriction

2. Applicant's election with traverse of Group II, Claims 1-10, 25 and 28-30 directed to SEQ ID NO:3 and 4, in Paper No. 13 (1/10/00), is acknowledged. The traversal is on the ground(s) that groups I-XVIII are not distinct but rather represent one single investitive concept warranting examination in a single application. This is not found persuasive because the inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventive concept of a hemopoietin receptor (G-CSF receptor) has been disclosed by Nagata et al. (see Ref. A). Because the special technical feature of Group I has been found in the prior art, a technical relationship does not exist between the claimed groups. Therefore, unity of invention is lacking. The inventions of Groups II-XVIII are drawn to products having materially different structures and functions, each defines a separate invention over the art. A search of groups I-XVIII would not be co-extensive particularly with regard to the literature search. An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. This application is informal in the arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(I) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

Appropriate correction is required.

4. Acknowledgment is made of applicant's claim for foreign priority based on application filed in Australia on 10/23/95, 12/22/95 and 9/996 numbered PN-6135, PN-7276 and PO-2208

respectively. It is noted, however, that applicant has not filed a certified copy of applications PN-6135, PN-7276 and PO-2208 as required by 35 U.S.C. 119(b).

5. The disclosure is objected to because of the following informalities:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78) as well as the relationship of instant application to the parent.

6. The drawings objected to because each Figure must described separately in the Brief Description of the Drawings. For example: a) Figure 1 should be labeled as Figure 1A, 1B, 1C, 1D, 1E and 1F and described in the Brief Description of the Drawings as Figure 1A-1F , or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1). Similarly, Figures 3, 4, 5, 7 should be labeled and described accordingly.

7. The application contains two sets of sequence listings, one presented originally as pages 47-57 of the specification and another set submitted as paper number 9, 1/6/99. Clarification is needed that both the sequences are the same and which one should be labeled as the copy.

8. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Sequences in Figures must be identified by their corresponding SEQ ID NO: and disclosed in the Brief Description of the Drawings.

Also application fails to comply with the Sequence Rules, 37 CFR 1.821 et seq., because claims 1 and 2 refer to an amino acid sequence without reference to a SEQ ID NO: identifier. Compliance with sequence rules is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 30 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

9. Claim 30 recite an animal cell but does not recite that the cell is isolated or purified. The claims as currently recited encompass naturally-occurring cells since the genetic construct of claim 10 reads on a naturally occurring chromosome. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated and purified" to overcome this rejection.

Claim Rejection, 35 U.S.C. 112, second paragraph

10. Claims 1-10, 25 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are indefinite because it is not clear what sequence of nucleotides encoding or complementary to a sequence encoding an hemopoietin receptor the claim is referring to so as to allow the metes and bounds of the claim to be determined. Reference must be made to the sequence by use of "SEQ ID NO:". Similarly claims 7-8 and 29 are indefinite because it is not clear which sequences are being referred to.

Claims 1- 4, 7-9 and 28-29 are indefinite because it not clear what is a "derivative of said receptor". "Derivative" has not been defined in the claims nor specification so as to allow the metes and bounds of the claim to be determined. Further the claim is indefinite because the term "derivative" carries no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated nucleic acid molecules.

The term "low affinity" in claims 3 and 28-29 is a relative term which renders the claims indefinite. The term "low affinity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "medium or high affinity" in claim 4 is a relative term which renders the claim indefinite. The term "medium or high affinity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 5, 8, 28 and 29 are indefinite because it is not clear when a receptor has a an "amino acid sequence substantially as set forth in" SEQ ID NO:4 so as to allow the metes and bounds of the

claim to determined. Further it is not clear when a receptor does not have an "amino acid sequence substantially as set forth in SEQ ID NO:4.

Claim 6, 7, 28 and 29 are indefinite because it is not clear when a receptor is has a "sequence of nucleotides substantially as set forth in" SEQ ID NO:3 so as to allow the metes and bounds of the claim to determined. Further it is not clear when a receptor does not have a "sequence of nucleotides substantially as set forth in" SEQ ID NO:3.

Claim 7 is indefinite because it is not clear what is a "functionally similar IL-13 receptor". Without a disclosure of the functions a receptor must possess to be considered similar the metes and bounds of the claim cannot be determined.

Claims 7-8 are indefinite because "low stringency conditions" are not specified. The metes and bounds of the group of sequences that would meet the limitations of the claim depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which DNA sequences remain specifically bound to a particular nucleic acid the metes and bounds of the claims cannot be determined without the disclosure of said conditions.

Claim 25 is indefinite because it is not clear what are "genetically acceptable carrier and /or diluents so as to allow the metes and bounds of the claim to be determined.

Claim 28-29 is indefinite because it appears that the "Western blot" is expressed in COS cells. The claim should be amended to read that the polypeptide, when expressed in COS cells, has a

molecular weight of from about 50,000 to about 70,000 Daltons as determined by Western blot analysis.

Claim 28-29 is indefinite because it is not clear what the polypeptide is a recombinant of so as to allow the metes and bounds of the claim to be determined. The genetic construct of claim 10, on which claims 28 and 29 depend, reads on a naturally occurring chromosome. It is suggested that claim 10 be amended to recite an expression vector instead of "genetic construct".

Claim 10 is rejected for depending upon an indefinite base (or intermediate) claim and fails to resolve the issues raised above.

35 U.S.C. § 112, first paragraph

11. Claims 1-10, 25 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA (SEQ ID NO: 3) encoding a haemopoietin polypeptide (IL-13) comprising SEQ ID :4, does not reasonably provide enablement for other DNA. The, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While the person of ordinary skill in the art would, in light of the specification be able to isolate DNA encoding a polypeptide encoding IL-13 (SEQ ID NO:3), wherein the polypeptide comprises an amino acid sequence of SEQ ID NO:4, the scope of the claims, which encompass other

nucleic acids derivatives encoding polypeptides are not enabled by the disclosure. The disclosure does not teach how to make such fragments, or to use a commensurate number of the DNA fragments which did not share IL-4 or IL-13 binding functions. Due to the large quantity of experimentation necessary to identify the polypeptides of instant invention, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said polypeptides, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations of SEQ ID NO:3 and 4) are also encompassed by the claim), and the breadth of the claim which fail to recite structural limitations, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

The hybridization conditions of claims 7 and 8 have not been specified and do not constitute a meaningful structural limitation. Due to the large quantity of experimentation necessary to identify the polypeptides with the structural and functional features of instant invention without any disclosure of the hybridization or wash conditions, the unpredictability of isolating proteins related to SEQ ID NO:s 4, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

The instant fact pattern (claims 7 and 8) closely resembles that in Ex parte Maizel, 27 USPQ2d 1662 (BPAI 1992). In Ex parte Maizel, the claimed invention was directed to compounds which were defined in terms of function rather than sequence (i.e., "biologically functional equivalents"). The only disclosed compound in both the instant case and in Ex parte Maizel was the

full length, naturally occurring protein. The Board found that there was no reasonable correlation between the scope of exclusive right desired by Appellant and the scope of enablement set forth in the patent application. Even though Appellant in Ex parte Maizel urged that the biologically functional equivalents would consist of proteins having amino acid substitutions wherein the substituted amino acids have similar hydrophobicity and charge characteristics such that the substitutions are "conservative" and do not modify the basic functional equivalents of the protein, the Board found that the specification did not support such a definition, and that the claims encompassed an unduly broad number of compounds. Such is the instant situation. Clearly, a single disclosed sequence does not support claims to any nucleic acid hybridizing to same, given the lack of guidance regarding what sequences would hybridize specifically to SEQ ID NO: 3, and not other, related sequences. Likewise (claims 10, 25 and 28-30), expression vectors, cells comprising the vector of claim 10 and process for producing protein using said vector are not enabled for these reasons given above.

Claims 1-10, 25 and 28-30 derivatives of SEQ ID NOS:3 and 4. The claims read not only on naturally occurring but also on non-naturally occurring proteins. Although derivatives IL-13 can be made said derivatives carry no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated nucleic acid molecules. Further the applicant has not disclosed which derivatives would be expected to retain activity or how to use a commensurate number of said variants that are inactive. Due to the large quantity of experimentation necessary to identify the mutant, variant and derivatives with the structural features of instant invention without disclosed

functional features, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said mutant, variant and derivatives, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations are also encompassed by the claim), undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

Claim Rejections, 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12 Claims 1-8 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by Kausch et al. (Ref B). Kausch et al. disclose the isolation of human and mouse chromosomes (column 5; Examples 1 and 2; claims 21, 26 and 29). The cell source are human and mouse cells (column 6, lines 5-15). Many chromosomes can be sorted at once (column 9, lines 29-43). Large amounts of pure chromosomes may be isolated (column 10, lines 22-25), and the DNA from the chromosome is used for transfection into host cell (column 10, lines 22-34). Claims 1-10, encompass chromosomal DNA because the claims recite nucleic acid comprising the nucleotide sequence of SEQ ID NO:11 or derivatives thereof and claim 30 encompasses animal cells having the genetic construct of claim 10.

The genetic construct of claim 10 reads on a nucleic acid encoding a haemopoietin receptor operably linked to a promotor capable of directing expression, such as that contained in chromosome. The disclosure of Kausch et al. meets the limitations of Claims 1-10 and 30 and because the host cell inherently contained the afore mentioned nucleic molecules in the purified and isolated chromosomes.

13. Claims 1-8 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (ref C). Lin et al. disclose the isolation of chromosomes from human lymphocytes (Fig. 2). Claims 1-10 and 30 encompass chromosomal DNA and cells containing chromosomal DNA because the claims recite nucleic acid comprising the nucleotide sequence of SEQ ID NO:3, encoding the polypeptide of SEQ ID NO:3 or derivatives thereof. The disclosure of Lin et al. meets the limitations of Claims 1-10 and 30 because the host cell inherently contained the afore mentioned nucleic molecules in the purified and isolated chromosomes.

14. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Nagata et al (Ref A). Negata et al disclose an isolated nucleic acid molecule comprising G-CSF, a human haemopoietin factor, (SEQ ID NO: 1) thereby meeting the limitation of claim 1.

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Thursday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
April 8, 2000

Gary L. Kunz
GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200